REMARKS

Reconsideration and withdrawal of the rejection of the claims of the above-identified application is respectfully requested.

Claims 1-15 having been cancelled and claim 16 having been amended, the claims pending in the above-identified application are claims 16-26.

Claims 1-15 have been cancelled solely to advance the prosecution of the application, and without disclaimer or prejudice to their further prosecution in an appropriately filed continuing application.

The amendment to claim 16 to recite that the carbohydrate fraction comprises an effective uptake-enhancing amount of a monosaccharide and/or a dissacharide is supported throughout the specification, e.g., at pages 22-28, particularly at page 22, lines 24-29 and page 23, lines 13-24 and by originally-filed claim 11. No new matter is added by this amendment.

The cancellation of claims 1-15 moots the Examiner's rejection of claims 1-5 and 8-11 and anticipated by Schmidl (U.S. Pat. No. 5,438,042).

At pages 3-7 of the Office Action, the Examiner rejected claims 1-26 as obvious over Skubitz et al. (U.S. Pat. No. 5,438,075)("Skubitz"). Insofar as this rejection may be applied to any of amended claims 16-26, it is respectfully traversed.

The Examiner applies Skubitz to claims 16-26 at pages 6-7 of the Office Action. The Examiner concedes that the Skubitz composition is an aqueous suspension and not in a dry form. While the Examiner states that Skubitz does not disclose "the exact ratio by weight percent carbohydrate to L-glutamine," the ratio can be calculated by adding up the amounts of carbohydrates in the "final suspension" disclosed at Col. 5, lines 9-16. Not counting glycerin, this calculation yields 50 wt-% L-glutamine and 32.8 wt-% carbohydrate (sucrose and sorbitol). Thus, glutamine is disclosed to be present in a 52% excess over carbohydrate, while claim 16 recites that carbohydrate is present in at least a 100% w/w excess over the glutamine.

At page 7 of the Office Action, the Examiner states that "it should be noted that the Skubitz et al. composition must have been prepared in solid form before water was added to form the suspension." However, this is <u>not</u> the case. The Examiner is urged to review Col. 5, lines 3-9 of Skubitz where it is disclosed:

> The suspension of glutamine was prepared by mixing 50 grams of L-glutamine (supplied as a crystalline powder by Ajinomoto USA, Inc., Raleigh, N.C.), with 4 parts of ORA-Sweet (Paddock Laboratories, Minneapolis, Minn.), 2 parts ORA-Plus (Paddock), and 2 parts water to yield a suspension of 500 mg/ml L-glutamine. The final suspension contained 500 mg/ml glutamine, 30% sucrose, 2.5% glycerin, 2.8% sorbitol, 0.04% citric acid, 0.36% NaPO4, 0.16% cellulose and carboxymethylcellulose, 0.04% carrageenan, and 0.04% xanthum gum.

The Examiner is requested to consider the enclosed homepage for Nolte GmbH, the European distributor for Ora-Plus® and Ora-Sweet® (updated Sept. 4, 2003). The product Ora-Sweet® is an aqueous "syrup vehicle," described as a clear liquid, that contains water, sucrose and sorbitol. Ora-Plus® is described as a "translucent, milky white, thioxotropic liquid." Thus, it is clear that Skubitz et al. prepared their aqueous suspension by combining water with these two other liquid vehicles and glutamine to form their liquid suspension.

Finally, the Examiner states that it would have been obvious to one of ordinary skill in the art to have used "any form of the composition that contains different ratios of the same ingredients used by Skubitz et al., depending on need such as the severity of the disease or condition and the age or weight of the patient."

However, the Examiner is urged to consider that, while these factors might cause the art worker to vary the dose of the Skubitz composition given to a particular patient, there is absolutely nothing in Skubitz that would motivate the art worker to both alter the weight ratio of carbohydrate to glutamine taught by Skubitz, and to prepare a dry composition based on this altered ratio. Any such motivation would be supplied by knowledge of Applicant's discovery that carbohydrates enhance delivery of glutamine to tissues, and Applicant's discovery is not available as prior art citable against the claims. Therefore, withdrawal of this rejection is appropriate and is respectfully requested.

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6903 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

ROBERT G. PETIT, II, PH.D. ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6903

Date 4-15-05

By _____
Warren D. Woessner
Reg. No. 30,440

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 15th day of April, 2005.

PATRICIA A. HULTMAN _____

Name

Signature

Nolte

Homepage

[Products] [About us]

European distributor for

Ora-plus, Ora-sweet, and Suspendol-S

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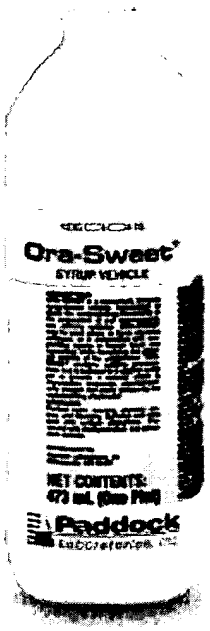
Update 21.09.04

PADDOCK COMPOUNDI



Ora-Sweet®
Syrup Vehicle

Ora-Sweet is a syrup vehicle used to simp the process of flavoring and sweetening extemporaneously compounded oral preparations. Ora-Sweet allows the pharmacist to formulate elegant, sweeten products with minimum time and maxim dependability. Ora-Sweet is the modern version of simple syrup flavored with a cit berry blend for a highly palatable taste.

Look to Paddock for All of Your Compounding Needs

Applications
Ora-Sweet may be used alone or in combination with other agents. Ora-Sweet will retain its flavoring properties when diluted up to 50% with water or suspending agents. Its versatility makes it ideal for the flavoring of:

- Pediatric preparations
- Geriatric preparations

How to Use
Ora-Sweet is the ideal flavoring and sweetening agent for many suspensions, but it is specially formulated to compliment Paddock's suspending vehicle Ora-Plus. Ora-Sweet and Ora-Plus can be combined in a 50/50 ratio to produce a tasty, elegant suspension.

Properties
Ora-Sweet contains sucrose which acts as a sweetening agent. Small amounts of glycerin and sorbitol are added to prevent "cap lock" problems common to most syrups. Its flavoring agents help increase palatability. Ora-Sweet is buffered to a slightly acidic pH to help diminish degradation of medicinal agents through oxidation.

Ingredients
Purified water, sucrose, glycerin, sorbitol (5%), flavorin
Buffering agents: Sodium phosphate and citric acid
Preservatives: Potassium sorbate and methylparab

Specifications
Appearance:	Clear liquid with a slight tint
pH:	Approximately 4.2
Taste:	Sweet citrus-berry flavor
Osmolality:	3240 mOsm/Kg

Size	NDC
473 mL (One Pint)	0574-0304-16

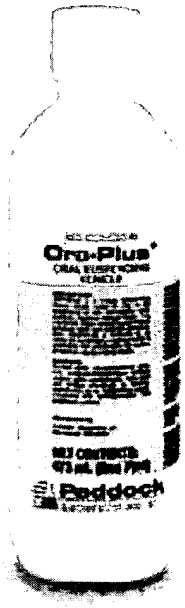
European distrib
Nolte G
49477 Ibbenbueren - Ger

Nolte

Ora Plus

[Start] [Ora Sweet] [Ora Plus] [Ora Sweet SF] [Suspendol]

PADDOCK COMPOUNDING



Ora-Plus®
Oral Suspending Vehicle

Ora-Plus is an oral suspending vehicle used to simplify the process involved in the extemporaneous compounding of oral suspensions. Medicated powder can be incorporated into Ora-Plus to form elegant, uniform, and physically stable suspensions.

Look to Paddock for All of Your Compounding Needs

Applications
Ora-Plus will retain its suspending properties when diluted up to 60% with water, flavoring agents, syrups or alcohol. Its versatility makes it ideal for:

- Pediatric suspensions
- Geriatric suspensions
- Naso-gastric preparations

How to Use
Ora-Plus can be used in combination with any flavoring syrup, but it is specially formulated to compliment Paddock's Ora-Sweet. Ora-Plus and Ora-Sweet can be combined in a 50/50 ratio to produce a pleasant tasting elegant suspension.

Properties
Ora-Plus is an aqueous-based vehicle consisting of a synergistic blend of suspending agents that have a high degree of colloidal activity. The suspending agents form a structured, gel-like matrix which suspend particles and allow for little settling. Ora-Plus is buffered to a slightly acidic pH to help reduce degradation of medicinal agents through oxidation. An anti-foam agent is incorporated into Ora-Plus to allow for vigorous shaking with minimal foam.

Ingredients
Purified water, microcrystalline cellulose, sodium carboxymethylcellulose, xanthan gum and carrageenan
Buffering Agents: Sodium phosphate and citric acid
Antifoaming Agent: Simethicone
Preservatives: Potassium sorbate and methylparaben

Specifications
Appearance: Translucent, milky white, thixotropic liquid with a pH of approximately 4.2

Taste: Very bland taste (no sweeteners or flavors)

Viscosity: Thixotropic. Approximately 1000 cps at 25°C via brookfield viscometer

Osmolality: 250 mOsm/kg

Size	NDC
473 mL (One Pint)	0574-0303-16

European distributor:
Nolte GmbH
49477 Ibbenbueren - Germany

SMART ALTERNATIVES

Paddock Laboratories, Inc.

Update 13.06.04